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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/652,745

08/29/2003

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048968-117961

1765

27148 7590 10/14/2009
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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/652,745	Applicant(s) SCHASTEEN ET AL.	
	Examiner Shobha Kantamneni	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75, 77-95, 114-117, 121-132 and 134-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 75, 77-95, 114-117, 121-132 and 134-137 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 05/26/2009, wherein claims 75, 114-117, 121, 124, 127, 130 have been amended, new claims 134-137 have been added. Applicant's amendment also canceled claims 76, 96-113, 133.

Applicant's cancellation of claim 133 overcomes the rejection of claim 133 under 35 U.S.C. 112, second paragraph, as being vague, and indefinite.

Applicant's amendment overcomes the rejection of claims 75, 77-80, 82, 85, 96-103 under 35 U.S.C. 103(a) as being unpatentable over VAN OOUEN (WO 99/04646, PTO-1449), in view of Dunn et al. (US 4,824,686, PTO-892).

Applicant's amendment overcomes the rejection of claims 75-82, and 96 under 35 U.S.C. 103(a) as being unpatentable over Paquet et al. (CA 1261855, PTO-892), in view of Dunn et al. (US 4,824,686, PTO-892).

Applicant's amendment overcomes the rejection of claims 75, 77, 97, 99-103, 113-117, 133 under 35 U.S.C. 103(a) as being unpatentable over Doerr et al. (Poultry Science, 74 (1), 23, 1995, PTO-892), in view of Rolow et al. (US 6,355,289, PTO-892).

Applicant's amendment overcomes the rejection of claims 75, 77-87, 90-93, 96-97, 99-104, 113, 115-119, 133 under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 4,824,686, PTO-892), in view of Enthoven et al. (Eur. Assoc. Anim. Prod. Proc., jan, 2002, EEAP, Cairo, PTO-1449).

Currently claims 75, 77-95, 114-117, 121-132, 134-137 are examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75, 77-87, 90-93, 115-117, 121-122, 124-125, 127-128, 130-131, 134-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 4,824,686, PTO-892), in view of Blake et al. (US 2,938,053, PTO-892), Buttin (International Pig Topics, PTO-1449), and further in view of Bland et al. (US 5,591,467).

Dunn et al. teaches a method of killing microbes in animal feed such as pig feed, cattle feed, or poultry feed comprising treating animal feed with a binary blend of formic acid and propionic acid (preservative composition). See column 1-column 2; column 5-column 6. It is also taught that using a specific blend of formic acid and propionic acid, synergism is observed in respect of both their antimold and antibacterial activity. See column 1, lines 30-35. It is also taught that the mixture of formic acid, and propionic acid is a more potent inhibitor of salmonella infections than formic acid alone. See column 6, lines 30-34. Dunn et al. teaches that the preservative composition can be applied to feedstuff to be preserved in the form of an aqueous solution of the blend or the blend can be impregnated on a solid carrier such as e.g. silica and then mixed with the feedstuff to be preserved. See TABLE 3, wherein Broiler feed is employed in the BioAdd Blend which contains formic acid, propionic acid, and sulfuric acid. It is also taught that the animal feed to which the preservative composition is applied may be pelleted or

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mash form. See column 1, lines 59-64. Dunn et al. also teaches that other C1-C4 aliphatic carboxylic acids have anti-mold activity and have been used as preservatives for crops and animal feedstuffs. See column 1, lines 10-15

Dunn et al. do not teach the employment of 2-hydroxy-4-(methylthio)butanoic acid in the preservative compositions therein.

The prior art references do not specifically teach the employment of organic acids such as lactic acid, butyric acid.

The prior art references do not teach the particular amounts of 2-hydroxy-4-(methylthio)butanoic acid, lactic acid, butyric acid.

Blake et al., teaches that Alimet, 2-hydroxy-4-(methylthio)butanoic acid has antimicrobial activity, antifungal activity and thus on mixing Alimet (2-hydroxy-4-(methylthio)butanoic acid) with food kills microbes. Blake et al. teaches that Alimet is used in poultry feed, and is more effective than methionine as a poultry nutrient. See column 1. Buttin et al. teaches that in addition to providing a methionine source, as an organic acid 2-hydroxy-4-(methylthio)butanoic acid reduce feed pH, and provides relatively strong acid effect with a pKa of 3.6 (formic acid pKa = 3.75), and an acid structure similar to lactic acid. Buttin also teaches that diet acidification is an alternative to antibiotic use in piglet diets.

Bland et al. teach that organic acids such as formic acid, propionic acid, butyric acid, lactic acid have antibacterial properties and kill bacteria in solution. See column 9, lines 5-10.

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It would have been obvious to a person of ordinary skill in the art at the time of invention to add 2-hydroxy-4-(methylthio)butanoic acid to the preservative composition taught by Dunn et al. because Blake et al., teaches that 2-hydroxy-4-(methylthio)butanoic acid is an effective nutrient in poultry feed, and Blake et al., Buttin et al. teaches that 2-hydroxy-4-(methylthio)butanoic acid has antimicrobial activity. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose such as for killing microbes in food. The idea for combining them flows logically from their having been used individually in the prior art as antibacterial agents. As shown by recited teachings of Dunn et al., and Blake et al., the instant claims contain agents such as hydroxy-methylthio butanoic acid, propionic acid, formic acid, useful as antimicrobial agents. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to add organic acids such as lactic acid, butyric acid to the preservative composition taught by Dunn et al. because Bland et al. teaches that lactic acid, butyric acid has antimicrobial activity. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Dunn et al., Blake et al., and Bland et al., the instant claims contain agents such as hydroxy-methylthio butanoic acid, propionic acid, formic

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acid, lactic acid, butyric acid useful as antimicrobial agents. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of 2-hydroxy-4-(methylthio)butanoic acid, organic acids employed in the compositions, since the optimization of effective amounts of known agents, is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Furthermore, as the combined teachings of Dunn et al., Blake et al., Bland et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, “the organic acid composition kills more Salmonella in the food compared to when the food is treated with any single organic acid that forms the organic acid composition”, “pH of less than about 5”, “pH of about 4 to about 5”, “pH of about 4.5”, and “improved odor” are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. Further, it is pointed out that Dunn et al. teach that the mixture of formic acid, and propionic acid is a more potent inhibitor of salmonella

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infections than formic acid alone i.e mixtures of organic acids is more potent than using a single organic acid.

Claims 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 4,824,686, PTO-892), in view of Blake et al. (US 2,938,053, PTO-892), Buttin (International Pig Topics, PTO-1449), in view of Bland et al. (US 5,591,467) as applied to claims 75, 77-87, 90-93, 115-117, 121-122, 124-125, 127-128, 130-131, 134-137 above, and in view of Pinski et al. (US 2002/0172737, PTO-892).

Dunn et al., and Blake et al., Bland et al. are applied as discussed above.

The prior art references do not specifically teach that the formulations therein are mixed with food for feeding animal such as aquaculture.

Pinski et al. teaches a particulate foodstuff which is effective for feeding aquatic life such as crustaceans, fish, shell fish, comprising a particulate nutrient feed and an antimicrobial agent which provides shelf life for the foodstuff of at least about 6 months. See page 1, paragraph [0009]. The antimicrobial agent therein is selected from propionic acid, salt of propionic acid, citric acid or salt thereof. See page 5, claim 8.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the formulation comprising 2-hydroxy-4-(methylthio)butanoic acid, organic acids taught by the combination of references to mix with feed for aquatic animal because Pinski teaches that the feed composition for feeding aquatic animals comprise antimicrobial agents.

One of ordinary skill in the art at the time of invention would have been motivated to employ the preservative composition taught by the combination of references in aquatic feed with reasonable expectation of obtaining aquatic feed formulations that have longer shelf life.

Claims 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 4,824,686, PTO-892), in view of Blake et al. (US 2,938,053, PTO-892), Buttin (International Pig Topics, PTO-1449), in view of Bland et al. (US 5,591,467) as applied to claims 75, 77-87, 90-93, 115-117, 121-122, 124-125, 127-128, 130-131, 134-137 above, and further in view of Friedman et al. (US 4,495,208, PTO-892).

Dunn et al., and Blake et al., Bland et al. are applied as discussed above.

The prior art references do not specifically teach that the formulations therein are mixed with food for feeding companion animal.

Friedman et al. teach that pet food for feeding pets such as dog food contains antibacterial agents.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the formulation comprising 2-hydroxy-4-(methylthio)butanoic acid, organic acids taught by the combination of references to mix with feed for companion animals because Friedman teaches that the feed composition for companion animals such as cats, and dogs contain antimicrobial agents.

One of ordinary skill in the art at the time of invention would have been motivated to employ the preservative composition taught by the combination of references in

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companion animal feed because antimicrobial agents are well known to be used in dog food formulations.

Claims 114, 123, 126, 129, 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 4,824,686, PTO-892), in view of Blake et al. (US 2,938,053, PTO-892), Buttin (International Pig Topics, PTO-1449), in view of Bland et al. (US 5,591,467) as applied to claims 75, 77-87, 90-93, 115-117, 121-122, 124-125, 127-128, 130-131, 134-137 above, and further in view of Rolow et al. (US 6,355,289, PTO-892).

The combination of references do not specifically teach the employment of phosphoric acid, and the particular amounts of said acid.

Rolow teaches a method of extending the shelf life of tortillas made from corn flour by adding mold growth inhibitors i.e preservatives or antimicrobial agents such as acetic acid, propionic acid, butyric acid, benzoic acid, phosphoric acid. See abstract; column 1, lines 55-58; column 3-column 4.

It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of the prior art, the instant claims contain antimicrobial agents, hydroxy-methylthio butanoic acid, formic acid, lactic acid, propionic acid, butyric acid, phosphoric acid. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of 2-hydroxy-4-(methylthio)butanoic acid, organic acids and acidulant employed in the compositions, since the optimization of effective amounts of known agents, is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Response to Applicant's arguments:

Applicant's arguments with respect to claim rejections have been considered but are not persuasive in view of the new ground(s) of rejection as discussed above.

Applicant's arguments that "The data supports the unexpected results of the currently claimed invention. In particular, the data indicates that propionic acid alone or HMTBA alone would not be effective against Salmonella in feed. The Applicants's currently amended claims recite a method of inhibiting or killing microbes comprising Salmonella in feed. The data indicates that the currently claimed invention is effective at inhibiting or killing microbes comprising Salmonella in feed, and is therefore surprising and unexpected over the individual ingredients." These arguments have been considered, but not found persuasive. It is pointed out that the synergistic effect for two organic acid formulations provided by the applicant attached to the Declaration, is not convincing because the data provided is for two compositions with particular

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concentrations of individual ingredients in the blend i.e blend OA 4, which is 0.15% lactic acid, 0.15% propionic acid, and 0.15% HMTBA; and blend OA 6, which is 0.1% lactic acid, 0.1% butyric acid, 0.1% propionic acid, and 0.15% HMTBA propionic acid alone for comparison. The independent claim for example 75 is not limited to only these individual concentration/amounts, and thus the according to claim 75 the composition can contain any amount of HMTBA, and any amounts of organic acids. For, example in the data provided by applicant HMTBA alone is effective in killing Salmonella when used at a concentration of 1 %. Thus, the synergistic effect does not hold for all or any amounts/concentration of the individual ingredients. Thus, the evidence in figure 7 is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients i.e amounts of ingredients in the claimed method. See MPEP § 716.02(d). Therefore, the evidence presented in the declaration herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

Applicant argues that “The data of record further establishes that propionic acid alone or HMBTA alone would have been insufficient for the currently claimed invention.” These arguments have been considered, but not found persuasive because Bland et al. teach that organic acids such as formic acid, propionic acid, butyric acid, lactic acid have antibacterial properties and are effective in killing Salmonella in solution.

Applicant argues that “Bland specifically teaches away by identifying that propionic acid and other organic acid combinations may be antimicrobial in solution, but are ineffective at killing Salmonella in feed.” These arguments have been considered,

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but not commensurate in scope with instant claims because instant claims are not limited to solid feed. Instant claims broadly recite food, and food can be in the form of solution. Bland et al. teach that organic acids such as formic acid, propionic acid, butyric acid, lactic acid have antibacterial properties and are effective in killing Salmonella in solution.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627